



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

April 1, 2004

Nicholas M. Fleischer, R.Ph., Ph.D.
Director of Biopharmaceutics
The Weinberg Group Inc.
1220 Nineteenth Street, N.W., Suite 300
Washington, DC 20036-2400

Dear Dr. Fleischer:

Your petition requesting the Food and Drug Administration declare that the drug product Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension 200 mg/28.5 mg and 400 mg/57 mg are suitable for submission as an Abbreviated New Drug Application was received by this office on 04/1/2004. It was assigned docket number 2004P-0157/CP 1 and it was filed on 04/1/2004. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management